S.N. 09/510,937

II. APPLICANTS' INVENTION

The present invention relates to a catheter balloon made of tube having a microstructure of nodes and fibrils such as porous expanded polytetrafluoroethylene (PTFE), further including a non-porous coating over the porous microstructure. The coating renders the balloon non-porous and thereby able to contain a desired inflating media (e.g., air or saline fluid). The thinness, flexibility and strength of the construction allow the resulting balloon to be collapsed to a small first diameter for insertion into a vascular conduit to a desired location at which it can be inflated to the maximum diameter of the tube in the fashion of a conventional polyethylene terephthalate (PET) catheter balloon. The balloon of the present invention is superior to such conventional balloons again due to its flexibility, thinness, strength and lubricious materials.

III. REJECTION OF CLAIMS 2 AND 12 UNDER 35 USC 112, SECOND PARAGRAPH.

The Examiner states that claims 2 and 12 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that "The term "fluorinated ethylene propylene" is indefinite." Applicants are further queried, with regard to FEP, "Do applicants employ these monomers as coatings?"

Technically, FEP is a copolymer rather than monomers (e.g., a blend of monomers). It is a melt-processable thermoplastic fluoropolymer that can be processed with conventional techniques involving heating to above the melt temperature of the polymer. A good summary description is provided in the "Polymer Technology Dictionary" (Tony Whelan, Chapman & Hall, First Edition, 1994), which states that "Molten FEP adheres well to other materials; has been used to join PTFE components to metal." The coating process referred to in claims 2 and 12 is described at p. 15, lines 1-24 of the specification of this patent application. The term "fluorinated ethylene propylene" is thus not indefinite, and is well understood by those of skill in the art of fluoropolymers. Its use as a coating for purposes of the present invention has also been made clear by the specification.

IV. REJECTION OF CLAIMS 1-20 UNDER 35 USC 103 AS UNPATENTABLE OVER KASPRZYK et al., WO 90/14406 IN VIEW OF GORE, US 4,187,390 AND HOUSE et al., US 4,877,661.

Kasprzyk et al teach catheters containing PTFE tubing in interlayers; the catheters have inelastic balloons. The Examiner notes that Kasprzk et al. fail to teach the use of adhesives, PTFE material that contains nodes and fibrils (porous expanded PTFE, or ePTFE), PTFE/PTFE structure or continuous coating.

S.N. 09/510,937

Gore teaches the manufacture of ePTFE including articles such as tubes and laminates of that material. House et al. teach modified ePTFE materials having 'bent' fibrils; these materials are useful in making articles useful for medical applications such as implantable tubular vascular grafts. Col. 2, lines 45-49 notes that the rapid recovery property of the material permits it to undergo repeated applications of tensile loads.

The Examiner concludes that all three references are analogous because they all deal with PTFE materials, and that it would be obvious to one of ordinary skill in the art to employ the PTFE materials of Gore in the catheters of Kaspyrzk et al., as suggested by House et al., in order to make the catheters strong (per Gore) and capable of withstanding repeated applications of tensile loads (per House et al.).

Applicants respectfully disagree, as follows. It is particularly important to note that the instant claims are directed to a tubular structure configured an inflatable balloon, and are not at all directed to a tubular catheter shaft. As medical devices, these balloons are typically affixed at one end to a catheter tubular shaft that is useful to deliver the balloon to a site within a living body at which it will be inflated to accomplish a therapeutical purpose. Once the balloon has been directed to the desired site, the catheter shaft is also used to deliver a suitable medium to the interior of the balloon to cause inflation (typically saline fluid). The claimed balloon is entirely different from the catheter shaft to which it is affixed. This balloon is, in a collapsed (non-inflated) state, folded up so as to present a minimal profile (transverse cross sectional area) during delivery through body passageways that are often of small inside diameter and sometimes tortuous routes. While the catheter shaft is also of small profile, it is typically relatively rigid to enable it to be controllably directed to the site at which it is desired to inflate a balloon (e.g., a coronary artery). The structural and mechanical requirements for a catheter shaft are thus entirely different from the balloon, which must also be of small cross sectional profile for delivery, but must be capable of achieving a much larger delivery when inflated. The catheter shaft delivering the inflation fluid must not be diametrically affected by the pressure of the delivery fluid, while the balloon must respond entirely differently to achieve the larger diameter necessary to accomplish the intended purpose (e.g., reopen an occluded or partially occluded blood vessel). It is therefore clear that constructions appropriate for a catheter shaft as taught by Kaspyrzk would not be useful for a catheter balloon as taught by the present invention.

Further, Kaspyrzk et al. teach the use of PTFE as a middle layer of a coaxial cable that forms a part of the catheter shaft, with the adjacent inner and outer layers being electrically conductive. While PTFE has a long history of use as a dielectric material, the particular use as an electrically insulating component in an electrically conductive catheter shaft would not be suggestive of the use of ePTFE in a catheter balloon. Indeed, Kaspyrzk et al., do not teach or suggest the use of PTFE in their catheter

S.N. 09/510,937

balloon (e.g., see Kaspyrzk et al. at p. 17, lines 30-33 which recites typical catheter balloon materials), and they do not teach or suggest the use of ePTFE in any fashion. Because Kaspyrzk et al. only teach the use of PTFE as a dielectric component in a catheter shaft, because they do not teach the use of PTFE in a flexible (foldable) balloon, and because they do not suggest the use of ePTFE for any purpose, there is no reason to combine Kasprzyk et al. with either of the other two references.

While Gore teaches that ePTFE can be laminated using various adhesives including FEP, he makes no suggestions that would direct one of skill in the art of catheter balloons to use FEP-coated ePTFE as a thin and flexible material for an inflatable catheter balloon. Likewise, while the ePTFE material of House et al. with its bent fibrils is highly flexible, the ePTFE of the present invention does not have need of such bent fibrils (e.g., see Figure 1 describing the microstructure of the ePTFE film used as the precursor material of the present invention). With regard to teaching of House et al. at col. 2, lines 45-49 to the effect that, as stated by the Examiner, "The materials' recovery properties permit them to undergo repeated applications of tensile loads", catheter balloons are not typically required to undergo repeated applications of tensile loads. While tensile strength is important in a catheter balloon (in particular, hoop strength), catheter balloons are typically only inflated one time and then discarded following deflation and withdrawal from a patient's vasculature. In short, there is simply no suggestion in either Gore or House et al., to use ePTFE coated to render it non-porous, in a tubular form configured specifically for use as an inflatable catheter balloon.

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,

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